Rapid Micro Biosystems

Certificate of Analysis

Product Name:	Environmental Monitoring Cassette: Tryptic Soy Agar with Lecithin, Polysorbate 80, Histidine and Sodium Thiosulfate		
Catalogue number:	ET80HT-100	**Manufacture Date:**	16Feb2021
Lot Number:	04721L6	**Expiration Date:**	16Nov2021

The above lot has been produced in a microbiologically controlled environment and irradiated in accordance with Rapid Micro Biosystems' Quality Systems. Representative samples were tested per Rapid Micro Biosystems' protocols and were found to meet the performance and physical characteristics release criteria for this product.

Physical Characteristics:

Test	Specification	Result
Media appearance	Light amber brown color, no surface blemishes	Satisfactory
pH[#]	7.3 +/- 0.2 at 25°C	Satisfactory

[#]Media pH will vary within the stated range depending on the age of the product and the type of pH meter and probe used.

Growth Promotion*:

Microorganism	ATCC®**	Result
Aspergillus brasiliensis	16404®	Satisfactory
Bacillus subtilis	6633®	Satisfactory
Candida albicans	10231®	Satisfactory
Pseudomonas aeruginosa	9027®	Satisfactory
Staphylococcus aureus	6538®	Satisfactory

*A standardized inoculum of the test organisms listed above was inoculated on selected cassettes. Growth was measured after 24-72 hours' incubation on the Growth Direct system at 30-35°C. Satisfactory results indicate recovery within 50-200% compared to a previously released batch.
** Test organisms from alternative equivalent reference organisations may be substituted as required.

Irradiation:

Irradiation Dose	Certified to be between 8-12.5 kGy
Sterility Evaluation	No growth detected at 5-7 days' incubation 32.5°C +/- 2.5°C

Country of origin is USA. Media components of animal origin used in the manufacture of this product are certified, by Rapid MicroBiosystems' suppliers, as sourced from BSE-TSE free countries, as identified by the United States Department of Agriculture (USDA). Certificates are held on file at Rapid MicroBiosystems.

Certificate results reported here were obtained at time of release. Product is for exclusive use with Rapid MicroBiosystems' Growth Direct system. Not for In Vitro Diagnostic use.

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Released by:

Release Date 03 MAR 2021

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